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EXAMINER

GABEL, GAIENE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/086,213	Applicant(s) MORGAN, CHRISTOPHER	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 47-56 and 60-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46, 57-59, 65 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/28/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 1, claims 1-46, 57-59, 65, and 66, without traverse, filed November 8, 2004 is acknowledged and has been entered. Claims 47-56, 60-64, and 67 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1-67 are pending. Claims 1-46, 57-59, 65, and 66 are under examination.

Abstract

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Priority

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application in the first sentence of the

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specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications and the current status of the parent application (i.e., abandoned, now US Patent Number) except when the reference is to a prior application of a CPA assigned the same application number.

Specification

4. The following Contents of Specification are not identified by subtitles as follows.
 - (a) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
 - (b) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the

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invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (c) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (d) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-46, 57-59, 65, and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting, "determining an analyte by means of luminescence assay" because it is unclear as to whether Applicant intends a qualitative assay, i.e. the presence of the analyte, or a quantitative assay, i.e. concentration of the analyte.

Claim 1 is confusing because the limitations recited in i) and ii) are part of the preamble which does not appear to be Applicant's intent, since the claimed method is said to comprise method steps recited in iii) and iv). Accordingly, it is unclear as to what precludes the method steps of iii) and iv) and whether the limitations recited in i) and ii) should be given patentable weight in accordance to the provisions of 35 USC 102 or 103, as method step limitations which preclude steps iii) and iv). Please clarify.

Claim 1, part i), has improper antecedent basis problem in reciting, "the donor species".

Claim 1, part i), is vague and indefinite in reciting, "in ... a solid phase" because it is unclear what structural embodiment Applicant intends to encompass, i.e. immobilized to, derivitized in, outside or distinct from being adsorbed to the solid phase.

Claim 1, part i) is confusing because it is unclear what is encompassed in the recitation of "an up-conversion medium", i.e. the donor species, or the combined structure formed by the donor species and the solid phase.

Claim 1, part ii), has improper antecedent basis problem in reciting, "the acceptor species".

Claim 1 is vague and indefinite in reciting, "capable of", in all occurrences because it fails to recite a positive limitation in the claim.

In claim 1, step iv), the recitation of "and/or" renders the claim indefinite because it is unclear whether the limitation following the phrase are part of the claimed invention.

Claim 1 is vague in reciting, "at least one of the donor species and an acceptor species" because it is unclear as to whether the "an acceptor species" is the same

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element as the previously recited "acceptor species" in the preamble, part ii) and step iv).

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete and confusing for omitting essential structural and functional cooperative relationships of elements and method steps, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. In this case, it is unclear what structural and functional cooperative relationship exist between the donor species, acceptor species, and the analyte because none of parts i) or ii) of the preamble or iii) or iv) of the method steps, recite adding or combining a sample suspected of containing an analyte with any of the elements set forth in the claim. Hence, it is unclear where or how in the method steps an analyte would have played a role in the luminescence assay so as to "cause a change in the excitation condition of the donor species or acceptor species". Please clarify.

Claims 2-46 have improper antecedent basis problems in reciting, "A method as claimed in claim ...".

Claim 3 is indefinite in reciting, "capable of" because it fails to recite a positive limitation in the claim.

Claim 3 lacks antecedent support in reciting, "the bound species". Additionally, it is unclear what "the bound species" is, in the context of what is recited in claim 1 from which it depends. Accordingly, it is unclear what structural and functional cooperative relationships exist between this "bound species" and the elements in claim 1 including 1) the donor species, 2) the acceptor species, and 3) the analyte.

Claim 6 is vague and indefinite in reciting, "an up-conversion phosphor designed to absorb long wavelength radiation" because it is unclear how the up-conversion phosphor is designed or modified to absorb long wavelength radiation. Perhaps, Applicant intends, "an up-conversion phosphor that absorbs long wavelength radiation".

Claim 7 lacks clear antecedent support in reciting, "species therein (as in the up-conversion medium)".

Claim 7 is indefinite in reciting, "required for up-conversion processes to be possible" because it fails to recite a positive limitation in the claim. Perhaps, Applicant intends, "required for up-conversion processes to take place".

Claim 9 is non-idiomatic and therefore confusing in reciting, "relies on"

Claim 9 is vague and indefinite because it is unclear what "an organic molecule" is, in the context of what is recited in claim 1 from which it depends. Accordingly, it is unclear what structural and functional cooperative relationships exist between this "organic molecule" and the elements in claim 1 including 1) the donor species, 2) the acceptor species, and 3) the analyte.

Claim 9 lacks clear antecedent support in reciting, "the original state".

Claim 10 has improper antecedent basis problem in reciting, "an organic molecule".

Claim 11 is indefinite in reciting, "appropriate matrix" because the term "appropriate" is a subjective term that lacks a comparative basis for defining its metes and bounds.

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Claim 12 lacks antecedent support in reciting, "the exciting radiation". If the exciting radiation is intended to be the "electromagnetic radiation" recited in claim 1, then it is suggested but not required to refer to the same element as "the electromagnetic radiation" because consistency in terminology used in a given set of claims to refer to a specific element is key in achieving clarity and definiteness under the provisions of 35 USC 112, second paragraph, and in obviating this rejection. Alternatively, if the "exciting radiation" is distinct from the "electromagnetic radiation", then it is unclear what "the exciting radiation" is, in the context of what is recited in claim 1 from which it depends. Accordingly, it is unclear what structural and functional cooperative relationships exist between this "the exciting radiation" and "the electromagnetic radiation".

Claim 12 is vague and indefinite because it is unclear what "one or more species within the medium" is, in the context of what is recited in claim 1 from which it depends. Accordingly, it is unclear what structural and functional cooperative relationships exist between the "one or more species" and the "one or more other species" and the elements in claim 1 including 1) the donor species, 2) the acceptor species, and 3) the analyte.

Claim 13 lacks clear antecedent support in reciting, "the primary absorbing species".

Claim 13 has improper antecedent basis problem in reciting, "the ytterbium ion".

Claim 14 has improper antecedent basis problem in reciting, "the absorbed energy".

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Claim 14 is vague and indefinite because it is unclear what "the absorbed energy" is, in the context of what is recited in claim 12 from which it depends.

Claim 15 lacks clear antecedent basis in reciting, "the excited species". Further, it is unclear what "the excited species" and "similar sites" are, in the context of what is recited in claim 1 from which it depends. Accordingly, it is unclear what structural and functional cooperative relationships exist between the "excited species" and the elements in claim 1 including 1) the donor species, 2) the acceptor species, and 3) the analyte.

Claim 16 lacks clear antecedent basis in reciting, "sites within the bulk of the medium" and "sites at or near the surface of the medium". Further, it is unclear what "sites within the bulk of the medium" and "sites at or near the surface of the medium" are, in the context of what is recited in claim 15 from which it depends and claim 1 from which it ultimately depends. Accordingly, it is unclear what structural and functional cooperative relationships exist between the "sites within the bulk of the medium" and "sites at or near the surface of the medium" and the elements in claim 1 including 1) the donor species, 2) the solid phase, 3) the acceptor species, and 4) the analyte.

Claim 16 lacks clear antecedent support in reciting, "the bound species".

Regarding claim 17, the phrase "for example" or "e.g." renders the claim indefinite because it is unclear whether the limitation following the phrase is part of the claimed invention. See MPEP § 2173.05(d).

Claim 21 is indefinite in reciting, "the assay is conducted in a format in which the analyte causes an increase in the degree of binding of the acceptor to the donor"

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because it is unclear what structural and functional cooperative relationships exist between the 1) the donor species, 2) the acceptor species, and 3) the analyte, and what the recitation intends, in the context of the limitations recited in claim 1 from which it depends.

Claim 22 lacks clear antecedent basis in reciting, "the action of an enzyme or other catalytic species".

Claim 22 is indefinite because it is unclear what the recitation of "by activation of coupling or uncoupling between donor and acceptor either by catalyzing formation or cleavage of a linkage between them ..." is, in the context of what is recited in claim 20 from which it depends and claim 1 from which it ultimately depends. Accordingly, it is unclear what structural and functional cooperative relationships exist between the elements and processes in the instant claim and the elements and method steps set forth in claims 1 and 20, including 1) the donor species, 2) the acceptor species, and 3) the analyte.

Claim 23 is indefinite in reciting, "the assay is conducted in a format in which the analyte causes an decrease in the degree of binding of the acceptor to the donor" because it is unclear what structural and functional cooperative relationships exist between the 1) the donor species, 2) the acceptor species, and 3) the analyte, and what the recitation intends, in the context of the limitations recited in claims 1 and 20 from which it depends.

Claim 24 is vague and indefinite because it is unclear how the solid phase is modified so as to facilitate binding of analyte. Does Applicant intend that the solid

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phase has antibodies or receptors bound thereto, so as to cause their complimentary binding partners, i.e. analytes, to bind.

Regarding claim 25, the phrase "or other recognition ligands" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "or other"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Claim 26 is indefinite for using parenthetical symbols because it is unclear whether the limitations within the parentheses are a part of the claimed invention.

In claim 26, the recitation of "and/or" renders the claim indefinite because it is unclear whether the limitation following the phrase are part of the claimed invention.

Claim 26 is ambiguous because it is unclear what Applicant intends to encompass in reciting, "acceptance properties" as used in the claim.

Claim 26 is indefinite in relation to claim 1 from which it depends because it is unclear what structural and functional cooperative relationships exist between "moiety bound to the solid phase of the donor species and 1) the donor species and 2) the acceptor species, and what the recitation intends, in the context of the limitations recited in claim 1 from which it depends. See also claims 28-30.

Claim 27 is indefinite in reciting, "the assay is used to monitor the formation of cleavage of a bond linking a quenching species or an enhancer of emission to the solid phase or to a luminescent moiety bound thereto" because it is unclear what the "quenching species" and the "enhancer of emission" are, in the context of the limitations recited in claim 1 from which it depends. Accordingly, it is unclear what structural and

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functional cooperative relationships exist between the “quenching species” and the “enhancer of emission” recited in the instant claim and 1) the donor species, 2) the acceptor species, and 3) the analyte, recited in claim 1.

Claim 32 is indefinite in reciting, “MOS”. Acronyms or abbreviations must be fully defined and recited at least one time in a set of claims.

Claim 35 is indefinite in reciting, “CCD”. Acronyms or abbreviations must be fully defined and recited at least one time in a set of claims. See also claim 42.

Claim 37 lacks antecedent support in reciting, “the exciting radiation”. If the exciting radiation is intended to be the “electromagnetic radiation” recited in claim 1, then it is suggested but not required to refer to the same element as “the electromagnetic radiation” because consistency in terminology used in a given set of claims to refer to a specific element is key in achieving clarity and definiteness under the provisions of 35 USC 112, second paragraph, and in obviating this rejection. Alternatively, if the “exciting radiation” is distinct from the “electromagnetic radiation”, then it is unclear what “the exciting radiation” is, in the context of what is recited in claim 1 from which it depends. Accordingly, it is unclear what structural and functional cooperative relationships exist between this “the exciting radiation” and “the electromagnetic radiation”.

Claim 41 is ambiguous in reciting, “the detector is designed to implement phase-sensitive detection ...” because it fails to recite a positive limitation in the claim. Perhaps, Applicant intends, “the detector is designed to perform phase-sensitive detection ...”.

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Claim 44 lacks antecedent support for the recitation of, "the sample for analysis".

Claim 46 is indefinite in reciting, "differently affected by binding of an energy acceptor" because it is unclear what structural and functional cooperative relationships exist between "the energy acceptor" in the instant claim and 1) the donor species, 2) the acceptor species, and 3) the analyte in claim 1, and what the recitation intends, in the context of the limitations recited in claim 1 from which it depends.

In claim 57, line 3, "form" should be --from--.

Claim 58 is indefinite in relation to claims 1 and 57 from which it depends in reciting, "analyte recognition molecules are provided" because it is unclear what the recitation intends to encompass, in the context of the limitations recited in claim 1. See also claim 59. Are these "analyte recognition molecules" intended to be the same as the "antibodies, lectins, and oligonucleotides" recited in claim 25.

Claim 65 is objected upon for depending from a non-elected claim.

Claim 65 is vague and indefinite in reciting, "determining an analyte by means of a luminescence assay" because it is unclear as to whether Applicant intends a qualitative assay, i.e. the presence of the analyte, or a quantitative assay, i.e. concentration of the analyte.

Claim 65, step i) lacks antecedent basis in reciting, "said solid phase" and "said donor species".

Claim 65, step ii) lacks antecedent basis in reciting, "said electromagnetic radiation".

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In claim 65, step iii), line 1 after "detecting luminescence", "is detected" should be deleted.

In claim 65, step iii), the recitation of "and/or" renders the claim indefinite because it is unclear whether the limitation following the phrase are part of the claimed invention.

In claim 65, second to the last line of the claim, after "said change", "in" should be deleted and --is-- should be inserted therefor.

Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete and confusing for omitting essential structural and functional cooperative relationships of elements and method steps, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. In this case, it is unclear what structural and functional cooperative relationship exists between the microarray, the donor species, the solid phase, the acceptor species, and the analyte so as to be able to conduct a determination of analyte as required by the preamble because none of parts i), ii), and iii) of the method steps, recite adding or combining a sample suspected of containing a desired analyte with any of the elements set forth in the claim. Claim 1 recites the sample as "including an acceptor species". Hence, it is unclear where or how in the method steps an analyte would have played a role in the luminescence assay so as to "cause a change in the excitation condition of the donor species or acceptor species". Please clarify.

Claim 66 has improper antecedent basis problem in reciting, "A method as claimed in claim 65".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-28, 30-46, 57-59, 65, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Zarling et al. (US Patent 5,736,410).

Zarling et al. disclose luminescence binding assays for performing sensitive detection of analyte. Zarling et al. provide use of donor species adsorbed into solid phase in the form of up-conversion labels (phosphors and organic dyes) to label binding reagents for detecting and quantitating the presence of analyte in a sample (see column 19, line 65 to column 21, line 5). Up-conversion labels are microcrystalline up-converting lanthanide phosphor particles or are encapsulated into solid phase (microspheres or microcrystalline matrix) produced by gel-sol process. The particles or solid phase is further coated with antibodies, lectins, or oligonucleotides (probe) (see column 10, lines 55-67, column 13, lines 47 to column 14, line 8, and column 22, lines 9-26). The solid phase may also be organic or inorganic, the surface of which is modified so as to facilitate binding of analyte and to protect the solid phase from dissolution in aqueous medium (coated with polycarboxylic acid, derivitized with functional groups, amination) (see column 13, lines 10-47). Additionally, the solid phase may be provided with a continuous, discontinuous, or partial coating of a (alkali) metal

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upon which polypeptide ligands and probes having up-converting labels are attached thereto (see column 13 and column 18, lines 48-60). The solid phase may further comprise a plurality of distinct binding components, as in a microarray of different oligopeptides affixed to a solid support, for use in detecting complementary binding interactions of analytes (see column 23, line 65 to column 24, line 38). The solid phase may also be in the form of paramagnetic particles which have a metal coating and which specifically have analyte (glycoprotein) binding molecules (immunoglobulins) capable of directly or indirectly binding acceptor species of the up-converting labels so as to bring them into close proximity with the metal (see column 25, lines 1-32). Up-conversion labels simultaneously or sequentially absorb multiphotons at a low frequency band and emit at a higher frequency band and can be differentiated on the basis of the excitation or emission wavelength spectra. Therefore, the labels can be used to detect and discriminate multiple analyte targets. Zarling et al. specifically teach that the up-converting labels absorb long wavelength excitation radiation and convert it to emit radiation at a shorter wavelength (one-half to one-third of the excitation wavelength) (see column 5, lines 27-57 and column 22, line 58 to column 23, line 30). Generally, the up-converting lanthanide phosphor particles are an activation couple comprising ytterbium as the donor species or primary absorbing species of electromagnetic radiation and erbium or thulium as the acceptor species (emitter center) upon which the adsorbed energy from the donor species is ultimately transferred to excite the acceptor species. The acceptor species are ions of erbium or thulium. The transfer of energy from the donor to the acceptor is detected by decrease in luminescence efficiency of the

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donor species. According to Zarling et al., optimal size of the phosphor particle can be selected on the basis of quantum efficiency data for the various phosphors which can be readily obtained from handbooks or by generating a standardization curve measuring quantum conversion efficiency as a function of particle size or photon densities (see column 13, line 64 to column 14 and 15, and Table 1). In practice, Zarling et al. teach irradiating the donor species with electromagnetic radiation to excite the donor species, then detecting luminescence in a defined spectral region of emission only by the donor species or the acceptor species wherein no absorption of radiation used to excite the donor species is measured. Zarling et al. specifically taught that the up-converting labels, characterized by excitation and emitted wavelengths that are typically infrared or visible portions of the spectrum, permit essentially total rejection of any non-specific background autofluorescence because the long wavelength excitation radiation is converted to emitted radiation at about one-half to one-third of the excitation wavelength. A detector requiring a filter may be necessary to block the excitation light. The presence of analyte causes a change in the excitation condition of either one of the donor species or the acceptor species as a result of direct binding, indirect binding or release from the solid phase. Assays, i.e. enzyme linked surface assays, can be performed as homogeneous or heterogeneous format. Zarling et al. also provide that the up-converting phosphors are used to magnetically or optically trap, i.e. electron-trapping phosphors, particles that comprise the analyte or the labeled probe. Up-conversion labels may also rely on excitation of organic molecule (sensitizing dye) to an excited state which relaxes to a metastable state or triplet state which transfers its

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energy to a dissolved to a dissolved molecular oxygen molecule to yield an excited singlet oxygen molecule. See column 5, line 27 to column 6, line 37, column 7, lines 27-65, column 13, lines 10-46, column 19, line 65 to column 21, line 5, column 23, lines 33-64, column 28, lines 17-53, and column 47, lines 16-21. Initially, the up-conversion medium requires a priming dose of energy to excite species therein to metastable levels (increase the doping levels) (see column 15, lines 44-54). Excitation sources include near-infrared multiple laser diodes, light emitting diodes, and continuous wave or pulsed semiconductor light emitting diodes. The detector may be a semiconductor diode, a linear charge-coupled device (CCD), a solid state imaging detector that uses an image intensifier or single photon imaging detector, an avalanche photodiode, or a detection system that uses periodically switched, gated or frequency modulated detector to implement lock-in detection, or a detection system that is designed to implement phase-sensitive detection in conjunction with a periodic excitation source. The detector can further be designed to have defined time periods (time gated) or equipped with solid-state fast optical shutter (see column 6, lines 8-37, column 15, line 60 bridging to column 16, and columns 31-32).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zarling et al. (US Patent 5,736,410) in view of Selvin et al. (US 5,622,821).

Zarling et al. has been discussed supra. Zarling et al. differ from the claimed invention in failing to teach a pre-existing label whereby luminescence is quenched by the action of analyte.

Selvin et al. disclose use of luminescent label (lanthanide chelates) in resonance energy transfer methods wherein luminescence is quenched by action of analyte (see column 2, lines 51-61 and columns 7 and 8).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Selvin in luminescence quenching of lanthanide ions to detect the presence of analyte into the method of Zarling which utilizes up-converting phosphors to qualitatively and quantitatively determine the presence of analyte because Selvin specifically taught that luminescence quenching in analyte detection methods is an obvious variation of detection technique conventionally known in the art.

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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